DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 2005

SonoScape, Inc.
% Mr. Bob Leiker
Quality & Regulatory Services
7263 Cronin Circle
DUBLIN CA 94568

Re: K052042
Trade Name: SonoScape SSI-1000/SSI-5000™
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: July 25, 2005
Received: July 28, 2005

Dear Mr. Leiker:

This letter corrects our substantially equivalent letter of August 9, 2005 regarding a wrong transducer number.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SonoScape SSI-1000/SSI-5000™, as described in your premarket notification:

Transducer Model Number

2P1, PA2.5 MHz Phased Array
L741, LA7.5 MHz Linear Array

C344, CLA3.5 MHz Curved Linear Array
MPTEE, 7-4 MHz/10mm/64 element Multi-Plane Transesophageal Phased Array
5P1, 7-4 MHz/10mm/64 element Phased Array
C611, 8-4 MHz/R11mm/128 element Micro-convex Array
6V1, 8-4 MHz/R11mm/128 element Transvaginal Micro-convex Array
10L1, 12-5 MHz/38mm/128 element Flat Linear Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

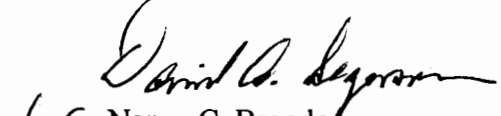
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound System Indications for Use

510(k) Number: _____

Device Name: SonoScape SSI-1000/SSI-5000
Diagnostic Ultrasound Pulsed Echo System
Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined	Tissue Harmonic Imaging
Opthalmic										
Fetal										
Abdominal		P	P	P		P	P		Note 1	N
Ob/GYN		P	P	P		P	P		Note 1	N
IntraOperative Neurological										
Pediatric		N	N	N	N	N	N		Note 1	N
Small Organ (breast, thyroid, testes)		P	P	P		P	P		Note 1	N
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		Note 1	N
Transesophageal		N	N	N	N	N	N		Note 1	N
Trans-Rectal		N	N	N		N	N		Note 1	N
Trans-Vaginal		N	N	N		N	N		Note 1	N
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular		P	P	P		P	P		Note 1	N
Laparascopic										
Muscular-Skeletal Conventional		P	P	P		P	P		Note 1	N
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication P = previously cleared by FDA E = added under Appendix E

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052042

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound System Indications for Use

510(k) Number: _____

Device Name: 2P1, PA2.5 MHz Phased Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined	Tissue Harmonic Imaging
Opthalmic										
Fetal										
Abdominal										
Ob/GYN										
IntraOperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		Note 1	P
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication P = previously cleared by FDA E = added under Appendix E

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052042

Prescription Use (Per 21 CFR 801.109) Indications For Use

Diagnostic Ultrasound System Indications for Use

510(k) Number: _____

Device Name: L741, LA7.5 MHz Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined	Tissue Harmonic Imaging
Opthalmic										
Fetal										
Abdominal										
Ob/GYN										
IntraOperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		P	P	P		P	P		Note 1	P
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular		P	P	P		P	P		Note 1	P
Laparascopic										
Muscular-Skeletal Conventional		P	P	P		P	P		Note 1	P
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication P = previously cleared by FDA E = added under Appendix E

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K052042

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound System Indications for Use

510(k) Number: _____

Device Name: C344, CLA3.5 MHz Curved Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined	Tissue Harmonic Imaging
Opthalmic										
Fetal										
Abdominal		P	P	P		P	P		Note 1	P
Ob/GYN		P	P	P		P	P		Note 1	P
IntraOperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication P = previously cleared by FDA E = added under Appendix E

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

Section 4.3

Indications For Use

510(k) Number K052042

Diagnostic Ultrasound System Indications for Use

510(k) Number: _____

Device Name: MPTEE, 7-4MHz/10mm/64 element Multi-Plane Transesophageal Phased Array Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined	Tissue Harmonic Imaging
Opthalmic										
Fetal										
Abdominal										
Ob/GYN										
IntraOperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		N	N	N	N	N	N		Note 1	N
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication P = previously cleared by FDA E = added under Appendix E

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052042

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound System Indications for Use

510(k) Number: _____

Device Name: 5P1, 7-4MHz/10mm/64 element Phased Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined	Tissue Harmonic Imaging
Opthalmic										
Fetal										
Abdominal										
Ob/GYN										
IntraOperative Neurological										
Pediatric		N	N	N	N	N	N		Note 1	N
Small Organ (breast, thyroid, testes)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		Note 1	N
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication P = previously cleared by FDA E = added under Appendix E

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052042

Prescription Use (Per 21 CFR 801.109)

Section 4.3 Indications for Use

Diagnostic Ultrasound System Indications for Use

510(k) Number: _____

Device Name: C611, 8-4MHz/R11mm/128 element Micro-convex Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined	Tissue Harmonic Imaging
Opthalmic										
Fetal										
Abdominal										
Ob/GYN										
IntraOperative Neurological										
Pediatric		N	N	N		N	N		Note 1	N
Small Organ (breast, thyroid, testes)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N		N	N		Note 1	N
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication P = previously cleared by FDA E = added under Appendix E

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K052042

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound System Indications for Use

510(k) Number: _____

Device Name: 6V1, 8-4MHz/R11mm/128 element Transvaginal Micro-convex Array Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined	Tissue Harmonic Imaging
Opthalmic										
Fetal										
Abdominal										
Ob/GYN		N	N	N		N	N		Note 1	N
IntraOperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal		N	N	N		N	N		Note 1	N
Trans-Vaginal		N	N	N		N	N		Note 1	N
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication P = previously cleared by FDA E = added under Appendix E

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

Section 4.3

Indications For Use 510(k) Number K052042

Diagnostic Ultrasound System Indications for Use

510(k) Number: K052042

Device Name: 10L1, 12-5MHz/38mm/128 element Flat Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined	Tissue Harmonic Imaging
Opthalmic										
Fetal										
Abdominal										
Ob/GYN										
IntraOperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		N	N	N		N	N		Note 1	N
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular		N	N	N		N	N		Note 1	N
Laparascopic										
Muscular-Skeletal Conventional		N	N	N		N	N		Note 1	N
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication P = previously cleared by FDA E = added under Appendix E

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052042

Prescription Use (Per 21 CFR 801.109)

AUG 9 - 2005

K052092

PREMARKET NOTIFICATION [510(k)] Summary

Trade Name: SonoScape Ultrasound System, SSI-1000/SSI-5000™ with 6V1 Micro-convex EndoCavity Linear Array, 10L1 Linear Array, MPTEE Multi-plane Trans-Esophageal Phased Array, 5P1 Phased Array, and C611 Micro-Convex Linear Array transducers.

Common Name: Diagnostic Ultrasound System and Transducers

Classification Names: Ultrasonic Pulsed Echo Imaging System, 90 IYO
Ultrasonic Pulsed Doppler Imaging System, 90 IYN
Diagnostic Ultrasound Transducer, 90 ITX

Manufacturer's Name: SonoScape Company Limited
4/F., Yizhe Building, Yuquan Road,
Nanshan, 518051, Shenzhen, China

Contact: Mr. Jinzhong Yao, President
Telephone: (86) 755-26722890
Fax: (86) 755-26722850

U.S. Agent: Bob Leiker
Quality & Regulatory Services, Inc.
Dublin, CA 94568

Predicate Devices: SonoScape SSI-1000/SSI-5000, K042369 and the GE LogiQ 500, K970901, K991611, and K010329

Device Description: The SonoScape SSI-1000/SSI-5000 ultrasound system is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The all digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in depth soft-menu control allows the advanced user to set the system for different situations.
The SonoScape System can be configured either as a portable (SSI-1000) model, or as a roll-around model on wheels (SSI-5000).

Intended Use: The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen; Pediatric; Small Organ (breast, tests, thyroid); heart soft tissue; Peripheral Vascular, Musculo-skeletal (conventional) and Urology.

Technological Characteristics

Display Modes	Single and dual 2-D; Display of Duplex 2-D/M-mode; 2-D/Pulsed Doppler and Triplex 2-D/CD/Pulsed Doppler image formats; Dual B and Color in real time
Measurements	Distance; area; circumference; calipers; velocity, PI, RI. Cardiac. OB and Vascular package
Principle of Operation	Applying high voltage burst to the Piezoelectric material in the transducer and detect the reflected echo to construct the 2-D B-mode, Doppler color, and Doppler spectrum image for diagnostic purpose.
Operating Controls	• TGC 8 slider, +/- 24dB • Depth Range: 3 to 24 cm • Image sector size: 32 lines to full B (256 lines) • Image Sector position: Steering within full maximum • B orientation flip: L/R key with marking on the screen • B Dynamic range control: preset 5 curves over 50-90 dB • Gray Scale Control: 8 Settings • Focal Number: 16 focal zone setting • B persistence: 30-90% recursive • Image Processing: Smoothing, edge enhancement • PW sweeping speed 2,4,8 sec over display. • PW Wall filter setting: 16 settings, 0.25 to 20% of PRF • PW sample volume: 0.5 to 10mm with 0.5mm step size. • PW/B update: with UPDATE key • PW cursor steering: Steer soft key • PW angle correction: 0 to 70 degree user control • PW trace: Peak, Mean • PW spectrum dynamic range: 5 preset curve over 15-48 dB • Spectrum baseline shift and invert • Color ROI setting: trackball and set key to control size and position • Color steering on flat probe: +, 0, - • Color Wall Filter: Color wall filter with 16 selection, 0.25-20% of PRF • Color & B priority: C-B priority soft menu • Color Packet size: preset per Exam range from 8 to 12 • Color spatial filter: preset per Exam, horizontal, vertical, off • Zoom factor: 1 to 10 continuously • Cine control: step, play backward, play continuously
Acoustic Output	Track 3; MI, TIS, TIC, TIB Derated Ispta: 720mW/cm2 maximum, TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190 W/cm^2 max
Display Annotations	Time/date/year; transducer type; power output in %; frames per second; persistence; and compression settings; image depth; patient name and ID; institution name; focal position; TGC curve display; Doppler & M scale in sec; Doppler angle correction cursor; EKG trace; probe tip temperature / angle for MPTEE; free form annotation anywhere on image; trackball controlled; selective or global erase of the display annotations, body markers with transducer annotations
Safety Compliance	IEC601-1 International Electrotechnical Comission; Medical Electrical Equipment IEC60601-2 International Electrotechnical Comission; Electromagnetic Compatibility